PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of	)	
	)	Group Art Unit 1642
NEEDLEMAN et al.	)	
	)	Examiner: Minh-Tam Davis
Serial No. 09/387,340	)	
	)	
Filed: August 31, 1999	)	Atty. Docket: MON-102.0-C
	)	(3119-C)(061765.00367)
Continued Prosecution Application	)	
Filed: January 4, 2002	)	

For: **AN IMMUNOLOGICAL PROCESS AND CONSTRUCTS FOR INCREASING THE HDL CHOLESTROL CONCENTRATION**

#31
8-5-03

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The Honorable Assistant Commissioner
for Patents
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, enclosed is Form PTO-1449 listing additional documents for consideration by the Examiner during the prosecution of this CPA application, together with a copy of each of the identified documents. This filing supplements those documents cited in the originally filed Information Disclosure Statement.

By submitting these documents, applicants do not admit that any are properly citable as prior art and reserve the right to challenge any basis on which they may be cited against the pending application and claims. Applicants request that the examiner review each of the cited documents.

In order to facilitate the examiner's review of these documents and not to limit the extent of that review, applicants provide a brief synopsis of several of the newly cited documents as follows:

Leff, BioWorld Today May 17, 1995 – Reports on a presentation made at a MIT Symposium describing an on-going project at T Cell Sciences with the objective of

inducing/developing an anti-atherogenic human plasma by vaccination.

Kwoh et al., WO 96/39168 published 12 Dec 1996 - Discloses CETP amino acid residues 466-476 and use of tetanus toxoid, Diphtheria toxoid, KLH, and ovalbumin as carriers. Claims {1} "A method of stimulating an immune response to increase HDL cholesterol in a mammal exhibiting low levels of serum HDL comprising administering to said mammal a composition comprising and immunogenic epitope of CETP."

Roy et al., J. Lipid Res 37:22-34 (1996) – "A new panel of 16 anti-human CETP mAbs has now been used to further probe the structure-function relationships of CETP. Of the new mAbs, 9 partially inhibit CETP-mediated CE transfer (24-43%) from HDL to LDL. The corresponding epitopes were mapped within the CETP primary structure by the reactivity of the mAbs with CETP variants having deletions or amino acid substitutions. Of the 9 new, neutralizing mAbs, 6 are specific for epitopes situated between residues 410-450 and two others for epitopes between residues 184-260 and 332-366, respectively. Epitopes of mAbs that do not influence CE transfer activity map to the regions 184-260, 261-331, and 367-409, respectively. When pairs of mAbs were tested for their abilities to mutually compete for binding to immobilized CETP, competition was observed for mAbs specific for epitopes that are distant in CETP primary structure. Together with previous mutagenesis studies, the data suggests that a carboxy terminal neutral lipid binding domain may be in close proximity to a lipoprotein binding region within native CETP." [from Abstract]

Smith et al., Medical Science Research 21: 911-912 (1993) - An immunogen comprising amino acid residues 131-142 of human CETP and keyhole limpet hemocyanin was injected into rabbits. Antibody raised bound to presumably native CETP and did not neutralize activity.

Stevens, US 4302386 (1980) – At Column, line 38 et seq., states "It has accordingly been discovered by virtue of this invention that it is possible to interfere with or treat various disease states or medical problems which are caused or influenced by certain polypeptides by active immunization of a male or female animal by the production and use of antigens formed by administration of modified polypeptides."

Thomas et al., FASEB J 12:a310, Thomas et al. (March 17, 1998) - Discloses anti-CETP antibody production in mice vaccinated intramuscularly with DNA plasmids containing human or rabbit CETP, driven by various disclosed promoter/enhancers.

Zegers et al., Eur. J. Immunol., 23: 630-634 (1993) – "In order to raise antibodies synthetic peptides are often coupled to a carrier protein to provide the necessary T cell determinants. The results indicate that a covalent bond between T cell and B cell determinants in general is needed to induce anti B cell determinant antibodies cross-reactive with the native protein." [from abstract]

Consideration of these and the other documents listed on the enclosed PTO-1449 Form are requested.

Respectfully submitted,

Dated: January 25, 2002

By: _____
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